

Exhibit 5



ANDA 211600

REQUEST GRANTED

Amneal Pharmaceuticals NY LLC
U.S. Agent for Amneal Ireland Limited
50 Horseblock Road
Brookhaven, NY 11719
Attention: Janie Gwinn
Senior Director

Dear Janie Gwinn:

This is in reference to your abbreviated new drug application (ANDA), submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act for Albuterol Sulfate Inhalation Aerosol, 90 mcg (base) per actuation.

We also refer to your correspondence received on December 13, 2023, [REDACTED].

I have carefully reviewed the materials you submitted in support of your request, as well as all other materials referenced herein.

[REDACTED].
Therefore, the revised GDUFA goal date of this ANDA is April 30, 2024.

If you have any questions, call Dhimo Vrusho, PharmD, Regulatory Project Manager at (240) 402 - 2882.

Sincerely,

{See appended electronic signature page}

Denise P. Toyer McKan, PharmD
Director, Division of Project Management
Office of Generic Drugs
Center for Drug Evaluation and Research



Denise
Toyer McKan

Digitally signed by Denise Toyer McKan

Date: 1/11/2024 09:06:56AM

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